

REMARKS

Claims 38-56, 76-86, 119-121, 123-140, 142-159, and 161-168 are pending in the patent application. Claims 38 and 76 have been amended to recite the phrase wherein the carbon monoxide associated with the raw meat is adapted to be removable after the second layer is removed "such that the color of the meat pigment is not fixed and turns brown in a natural time period upon removal of the second layer." Claims 119, 138 and 157 have been amended to recite the phrase that the carbon monoxide associated with the raw meat is adapted to be removable "such that the color of the meat pigment is not fixed and turns brown in a natural time period upon opening the package." Support for these amendments may be found at, for example, page 12, lines 2-12 and the examples of the present application. No new matter has been entered. After entry of these amendments, claims 38-56, 76-86, 119-121, 123-140, 142-159, and 161-168 remain in the patent application.

The Applicants are also submitting herewith evidence in the form of a 37 C.F.R. §1.132 declaration by one of the co-inventors Mr. Gary R. DelDuca ("the DelDuca Third Declaration") (Exhibit 1) to assist in showing the non-obviousness of the invention. The Applicants note that Mr. DelDuca previously submitted two declarations ("the DelDuca First and Second Declarations")¹ to assist in explaining the invention and showing the non-obviousness of the invention.

I. 35 U.S.C. § 103(a) Rejections

As acknowledged by the Examiner, U.S. Patent No. 5,686,127 to Stockley ("Stockley") does not disclose, teach or suggest the use of carbon monoxide (CO). *See* page 3 of the Office Action. The Office Action applies a number of references -- U.S. Patent No. 3,459,117 to Koch ("Koch"); U.S. Patent No. 4,522,835 to Woodruff ("Woodruff"); U.S. Patent No. 5,629,060 to Garwood ("Garwood"); and U.S. Patent No. 6,042,859 to Shaklai ("Shaklai") in an attempt to cure this deficiency in Stockley. It would not have been obvious to combine Stockley in view of

¹ The DelDuca First Declaration was filed with the Amendment and Response to Office Action Dated May 7, 2003. The DelDuca Second Declaration was filed with the Amendment and Reply to Office Action Dated June 14, 2004.

other references such as Koch, Woodruff, Garwood and/or Shaklai to arrive at the present invention.

II. Applicants Previously Presented Evidence Of Non-Obviousness Of Independent Claims 38, 76, 119, 138 and 157

Assuming, *arguendo*, that a *prima facie* case has been presented (which Applicants believe is not the case), the Applicants previously submitted evidence of non-obviousness in the form of (a) one declaration in the Amendment and Response to Office Action that was filed on May 7, 2003 -- the DelDuca Declaration (Exhibit A) and (b) two declarations in the Amendment and Reply To Office Action Dated June 14, 2004 -- the Hunt Declaration (Exhibit 1) and the DelDuca Second Declaration (Exhibit 2). Some of the evidence presented was directed to the understanding that those of ordinary skill in the art, prior to the Applicants' invention, believed that CO "fixed" the color of the meat pigment.

A. Prior To The Applicants' Invention, Those Of Ordinary Skill In The Art Believed That CO Fixed The Color Of The Meat Pigment

Specifically, the Applicants submitted evidence that prior to the Applicants' invention, those of ordinary skill in the art believed that CO "fixed" the color of the meat pigment:

(a) CO not allowed with fresh meat in the U.S. since at least 1962, until Applicants came up with novel approaches of using CO in modified atmosphere packaging (MAP) systems that avoided the concern of "fixing" the meat color;

(b) In a 1962 letter, the FDA told a Whirlpool representative that it might need additional data "to establish that the treatment of meat would not serve to cause the meat to retain its fresh red color longer than meat not so treated" and that the FDA has a question "concerning possible deception of the consumer where treatment of the meat leads to longer retention of the fresh red color.";

(c) A previously applied reference in this application "The Storage Life Of Beef And Pork Packaged In An Atmosphere With Low Carbon Monoxide And High Carbon Dioxide" from *Meat Science* to Sorheim et al. ("Sorheim") disclosed that its meat packaging systems with a

modified atmosphere of “0.4% CO/60% CO₂/40% N₂ had a bright stable red colour that lasted beyond the time of spoilage.” Abstract of Sorheim; and

(d) Dr. Hunt, who has extensive experience in the processing of meats using modified atmosphere packaging, stated that it was understood by those skilled in the art that CO fixes (creates a stable form of myoglobin that could mask spoilage) the color of the meat pigment to red.

B. The Applied References Of Shaklai And Koch Do Not Teach Or Suggest That The Use Of CO Turns Meat Pigment Brown In A Natural Time Period

In response to the overwhelming submitted evidence that those of ordinary skill in the art believed that CO “fixed” the color of the meat pigment, the Office Action states that “the prior art (e.g. Koch *et al.* and Shaklai) teaches that CO ‘fixes’ the color of the *surface* layer of the meat for only a finite number of days.” Page 10 of the Office Action (emphasis in original).

Neither Shaklai nor Koch teaches or suggests the claimed limitation “wherein the carbon monoxide associated with the raw meat within the package is adapted to be removable such that the color of the meat pigment is not fixed and turns brown in a natural time period upon removal of the second layer” that is specifically recited in independent claims 38 and 76. Neither Shaklai nor Koch teaches or suggests the claimed limitation “wherein the carbon monoxide associated with the raw meat within the package is adapted to be removable such that the color of the meat pigment is not fixed and turns brown in a natural time period upon opening the package” that is specifically recited in independent claims 119, 138 and 157. Furthermore, there is no motivation to combine Shaklai and/or Koch with the other applied references in the pending rejections.

1. Shaklai Teaches That CO “Fixes” The Color Of The Meat Pigment (I.e., Extends Color Life)

Since Shaklai teaches that CO “fixes” the color of the meat pigment after exposure to the atmosphere, there would be no motivation to one of ordinary skill in the art to combine Shaklai with Stockley, Koch, Garwood and Woodruff.

Specifically, Shaklai discloses exposing raw meat to an atmosphere consisting essentially of CO in which the meat is “completely immersed or saturated” with CO. *See* col. 5, lines 29-37. “More specifically, a cross-section of meat is completely immersed in or saturated to its core

with carbon monoxide from the exposed surfaces through the entire cross-section (thickness) including its core region and retains the carbon monoxide until the meat is cooked. Thus, as stated above, the meat is preserved throughout its thickness.” Col. 5, lines 38-43 of Shaklai.

Shaklai continues by stating that “[p]ractically all of the carbon monoxide (over 99.9%) taken up by meat will be maintained as hemoglobin and myoglobin (Hb/Mb) bound forms.” Col. 5, lines 57-59. Shaklai also discloses that “[b]oth hemoglobin and myoglobin bind carbon monoxide much more strongly than oxygen.” Col. 5, lines 66-67. “It is thought that the mechanism for carbon monoxide preserving of meat is the much greater affinity of myoglobin for carbon monoxide than for oxygen.” Col. 6, lines 26-28 of Shaklai.

It is known to those of ordinary skill in the art that when hemoglobin in the red blood cells is exposed to CO, the CO has an affinity 200 times greater than oxygen does with hemoglobin.² Therefore, one of ordinary skill in the art would expect that CO “fixes” the color of the meat pigment past its natural time period upon exposure to the atmosphere. DelDuca Third Decl. ¶ 4. In other words, because of the hemoglobin’s high affinity towards CO, the pigment of the meat, prior to Applicants’ invention, would not have been expected to degrade in a natural time period. DelDuca Second Decl. ¶ 4.

The examples of Shaklai also support that the meat pigment is “fixed” beyond its natural time period. Specifically, Example 4 of Shaklai (mentioned at page 5 of the Office Action) discloses that (a) meat treated with CO on day 14 had only a surface (less than 1 mm deep) being brown, while (b) meat treated with air was dark brown throughout. Col. 9, lines 40-50. Thus, it is clear that the meat pigment in Example 4 was “fixed” because it extended the color of meat pigment past its natural time period after being exposed to the atmosphere. This is further illustrated in Example 3 of Shaklai where the air-treated meat and CO-treated meat had different colors – the air-treated meat after 3 days was all brown and the CO-treated meat was a wine-red color. Col. 9, lines 10-19. Example 2 of Shaklai mentioned at page 5 of the Office Action also does not support that meat pigment is not “fixed” beyond its natural time period (air-treated samples were brown and CO-treated samples were a bright wine red after 24 hours). Col. 8, line 50-col. 9, line 5.

² See, e.g., Color Atlas & Textbook of Hematology, Wm Platt, 2nd edition 1979 (Exhibit 2) and DelDuca Third Decl. ¶ 4.

The Office Action asserts that Shaklai is being relied to fix the color of the surface layer of the meat for only a finite number of days. Page 10 of the Office Action. This ignores the evidence in the above examples that Shaklai discloses that the color of the meat pigment is fixed. There is no expectation in Shaklai that by applying the levels disclosed in Woodruff that the meat would brown in a natural time period.

Thus, because Shaklai discloses “fixing” the color of the meat pigment, there would be no motivation to one of ordinary skill in the art to combine Shaklai with Stockley, Koch, Garwood and Woodruff as in the pending rejections because Shaklai discloses “fixing” the color of the meat pigment.

B. Koch Does Not Teach Or Suggest That The Use Of CO Turns Meat Pigment Brown In A Natural Time Period

Since Koch does not teach or suggest that the use of CO turns meat pigment brown in a natural time period after removal of its CO-containing film, there would be no motivation to one of ordinary skill in the art to combine Koch with Stockley, Shaklai, Garwood and Woodruff as in the pending rejections.

Specifically, Koch discloses wrapping meat with a CO-containing film such that CO is transferred from the film to contact the surface of the meat. *See*, abstract. An object of Koch is to include a relatively small quantity of CO that is gradually released from the CO-containing film. Col. 2, lines 18-22. Koch discloses (a) covering primal cuts made at a slaughterhouse with a CO-containing film, (b) removing the CO-containing film at the retail outlet, and (c) cutting the primal cuts into individual steaks, roasts, etc. Col. 3, lines 4-8.

Since Koch discloses a large quantity of meat (primal cuts) exposed to a small quantity of CO, it would not be reasonable that the non-surface meat pigments of the primal cuts would have been exposed to CO. *See* DelDuca Third Decl.¶ 8.

First, Koch does not disclose the exact weight of the primal cuts of meat. “Primal” cuts of meat at the time of the Koch disclosure (late 1960’s), however, generally refers to sections of meat from anywhere between about 50 and 150 or more lbs. DelDuca Third Decl.¶ 7. The term “subprimal” cuts of meat is used today and generally refers to cuts of meat from about 15 to about 20 lbs. *Id.* Thus, it is clear that the term primal cuts of meat in Koch refers to a large quantity of meat. *Id.*

Second, the disclosure of Shaklai with 100% CO (as compared to the small quantity of CO in Koch) took over 7 days to saturate a small piece of meat with CO. Specifically, in Example 3 of Shaklai, 0.5 to 1.5Kg (about 1.4 lbs to about 4.2 lbs) took 7 days upon exposure to 100% CO to turn the meat pigment to carboxymyoglobin. *See* col. 9, lines 11-28 of Shaklai and DelDuca Third Decl.¶ 8. It would not be reasonable to one of ordinary skill in the art that a 50-150 lb piece of meat disclosed in Koch that had been exposed to a small quantity of CO would turn the non-surface meat pigments to carboxymyoglobin. DelDuca Third Decl.¶ 8.

Therefore, when the primal cuts of meat of Koch were cut at the retail outlet into individual steaks and roasts, the meat pigments of such individual steaks and roasts had not been exposed to the CO from the CO-containing film. *Id.* It would be expected that the individually cut steaks and roasts sections of Koch that were not exposed to CO would degrade in a manner similar to other similar cuts of steaks and roasts that had also not been exposed to CO. DelDuca Third Decl.¶ 9. Thus, Koch teaches that meat pigment in the form of individual steaks and roasts not exposed to CO in the CO-containing film would degrade in a similar manner of steaks and roasts not treated with CO. *Id.* Thus, Koch does not teach or suggest that the use of CO turns meat pigments brown in a natural time period after removal of the CO-containing film. *Id.*

Since Koch does not teach or suggest that the use of CO turns meat pigment brown in a natural time period after removal of the CO-containing film, there would be no motivation to one of ordinary skill in the art to combine Koch with Stockley, Garwood, Woodruff and Shaklai as in the pending rejections.

In summary, neither Shaklai nor Koch teaches or suggests that the meat pigment upon exposure to CO does not “fix” the color of the meat pigment after exposure to the atmosphere.

IV. Independent Claims 38, 76, 119, 138 and 157

Therefore, the submitted evidence summarized above indicates that prior to the Applicants’ invention, those of ordinary skill in the art believed that CO “fixed” the color of the meat pigment after exposure to the atmosphere.

The only apparent mention about the submitted evidence summarized above in this Office Action is that patent law is independent from FDA regulatory laws. *See* pages 10, 11 of the

Office Action. The Office Action is silent on Sorheim, which clearly states that CO in the amount of 0.4% used in a meat-packaging system had a bright red color that lasted beyond the time of spoilage. The Office Action is also silent on the 1962 letter to Whirlpool about the lack of data showing that the color of the meat pigment is not being fixed. The Office Action is also silent about the statement of Dr. Hunt, who is one skilled in the art, that it was understood by those skilled in the art that CO fixes the color of the meat pigment. The applied references of Koch and Shaklai do not alter that conclusion.

It would, therefore, be expected prior to the Applicants' invention that the CO levels disclosed in Woodruff would "fix" the color of the meat pigment after exposure to the atmosphere. Thus, there would be no motivation to combine Stockley, Koch, Garwood, Woodruff, Shaklai or any combination thereof.

Additionally, the Applicants presented compelling evidence directed to long-felt need in the Amendment and Response to Office Action dated on June 14, 2004 that further supports the non-obviousness of the present invention.

Therefore, independent claims 38, 76, 119, 138 and 157 are not obvious in view of Stockley, Koch, Woodruff, Garwood, Shaklai or any combination thereof and, thus, should be in a condition for allowance.

V. Dependent Claims 39-56, 77-86, 120, 121, 123-137, 139, 140, 142-156, 158, 159 and 161-168

Dependent claims 39-56, 77-86, 120, 121, 123-137, 139, 140, 142-156, 158, 159 and 161-168, which depend directly or indirectly on independent claim 38, 76, 119, 138 or 157 are not obvious in view of Stockley, Koch, Woodruff, Garwood, Shaklai or any combination thereof for at least the same reasons discussed with respect to claims 38, 76, 119, 138 and 157. Thus, claims 39-56, 77-86, 120, 121, 123-137, 139, 140, 142-156, 158, 159 and 161-168 should be in a condition for allowance.

VI. Conclusion

The Applicants submit that the claims are in a condition for allowance and action toward that end is earnestly solicited. It is believed that no fees are due; however, should any additional fees be required (except for payment of the issue fee), the Commissioner is authorized to deduct the fees from Jenkins & Gilchrist, P.C. Deposit Account No. 10-0447, Order No. 47097-01106USC1.

Respectfully submitted,

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